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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,624

04/09/2004

Michael John Dunkley

0197.00

8935

21968 7590 01/26/2007  
NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER

ALI, SHUMAYA B

ART UNIT

PAPER NUMBER

3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/821,624

Applicant(s)

DUNKLEY ET AL.

Examiner

Shumaya B. Ali

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-20, 27-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of Claims*

Claims 1-33 are pending in the instant application. Claims 13, and 21-26 remain withdrawn as being drawn to a non-elected species.

### *Response to Amendments*

No amendment has been filed in response to the office action dated 1/11/06.

### *Response to Arguments*

Applicant's arguments with respect to claims 1-12, 14-20, and 27-33 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-12, 14-20, 27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Valentini et al. US 4,069,819.**

**As to claim 1**, Valentini discloses an aerosolization apparatus (see fig.2) comprising: a housing defining a chamber (B) having one or more air inlets (H), the chamber being sized to receive a capsule (C) which contains an aerosolizable pharmaceutical formulation (col.1 line 49);

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a puncturing mechanism (fig.3, M-T) within the housing, the puncturing mechanism comprising an alignment guide (L) and a puncture member (D), wherein the alignment guide comprises a surface (bevel depicted at one end of L, see labeled fig.3 attached below) adapted to contact the capsule while the puncture member is advanced into the capsule to create an opening (col.2 lines 65-68, col.3 lines 1-10) in the capsule, and wherein at least a portion of the surface is sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule (see labeled fig.3); and an end section (A) associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule (col.3 lines 10-16).

**As to claim 2,** Valentini discloses wherein the surface is sloped at an angle, which is from 35 to 55 degrees relative to the longitudinal axis of the capsule (see labeled fig.3).

**As to claim 3,** Valentini discloses wherein the surface is sloped at an angle, which is from 37 to 50 degrees relative to the longitudinal axis of the capsule (see labeled fig.3).

**As to claim 4,** Valentini discloses wherein the surface is sloped at an angle of about 45 degrees relative to the longitudinal axis of the capsule (see labeled fig.3).

**As to claim 5,** Valentini discloses wherein the puncturing mechanism is at least partially within the chamber (see fig.2).

**As to claim 6,** Valentini discloses wherein surface comprises a passageway (fig.2, H) and wherein the puncture member slides (col.1, lines 16-49, col.2 lines 30-37) within the passageway.

**As to claim 7,** Valentini discloses wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the longitudinal axis of the puncture member (see labeled fig.3).

**As to claim 8,** Valentini discloses wherein the surface is sloped at an angle which less than 55 degrees relative to the longitudinal axis of the chamber (see labeled fig.3).

**As to claim 9,** Valentini discloses wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to an inhalation direction (see labeled fig.3).

**As to claim 10,** Valentini discloses wherein the surface is moveable (col.2 lines 65-68) within the chamber.

**As to claim 11,** Valentini discloses wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the direction of movement of the surface (see labeled fig.3).

**As to claim 12,** Valentini discloses wherein the surface comprises one or more protrusions and wherein the one or more protrusions (see labeled fig.3) are adapted to contact the capsule (col.2 lines 65-68).

**As to claim 14,** Valentini discloses wherein the end section is removably connected to the housing and wherein the end section may be removed from the housing to provide access to the chamber (col.2 lines 24-30).

**As to claim 15,** Valentini discloses wherein the puncture mechanism comprises a pair of puncture members (see fig.3, D).

**As to claim 16**, Valentini discloses wherein the puncture member is adapted to puncture only one end of the capsule (since puncture member is situated only one end of the device, it inherently punctures one end of the capsule).

**As to claim 17**, Valentini discloses wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (see fig.5).

**As to claim 18**, Valentini discloses wherein the width of the chamber is less than the length of the capsule (see fig.5).

**As to claim 19**, Valentini discloses wherein the inlet is shaped to create a swirling airflow within the chamber (col.3 lines 11-16).

**As to claim 20**, Valentini discloses an aerosolization apparatus (fig.2) comprising a housing defining a chamber (B) having one or more air inlets (H), the chamber being sized to receive a capsule (C) which contains an aerosolizable pharmaceutical formulation (col.1 line 49); a puncturing mechanism (fig.3, E) within the housing, the puncturing mechanism comprising an alignment guide (L) and a puncture member (D), wherein the alignment guide comprises a surface (bevel depicted at one end of L, see labeled fig.3 attached below) adapted to contact the capsule while the puncture member is advanced into the capsule to create an opening in the capsule (col.2 lines 65-68, col.3 lines 1-10), and wherein the surface comprises one or more protrusions (see labeled fig.3) for contacting the capsule, and an end (A) section associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule (col.3 lines 10-16).

As to claim 27, Valentini discloses wherein surface comprises a passageway and wherein the puncture member slides within the passage (col.1 lines 46-49, col.2 lines 46-54).

As to claim 28, Valentini discloses wherein the inlet is shaped to crease a swirling airflow within the chamber (col.3 lines 11-16).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claimed 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. US 4,069,819.**

As to claims 29,30,33, and 34, Valentini lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps (see above rejection cited for claims 1 and 6). Thus, the method steps as cited in claims 29 and 30 would have been obvious result of using the apparatus of Valentini.

As to claims 31 and 32, Valentini lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps (see above rejection cited for claims 20 and 27). Thus, the method steps as cited in claims 31 and 32 would have been obvious result of using the apparatus of Valentini.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Claim 1 recites the limitation "the longitudinal" in line 8. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

### ***Conclusion***

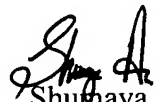
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.




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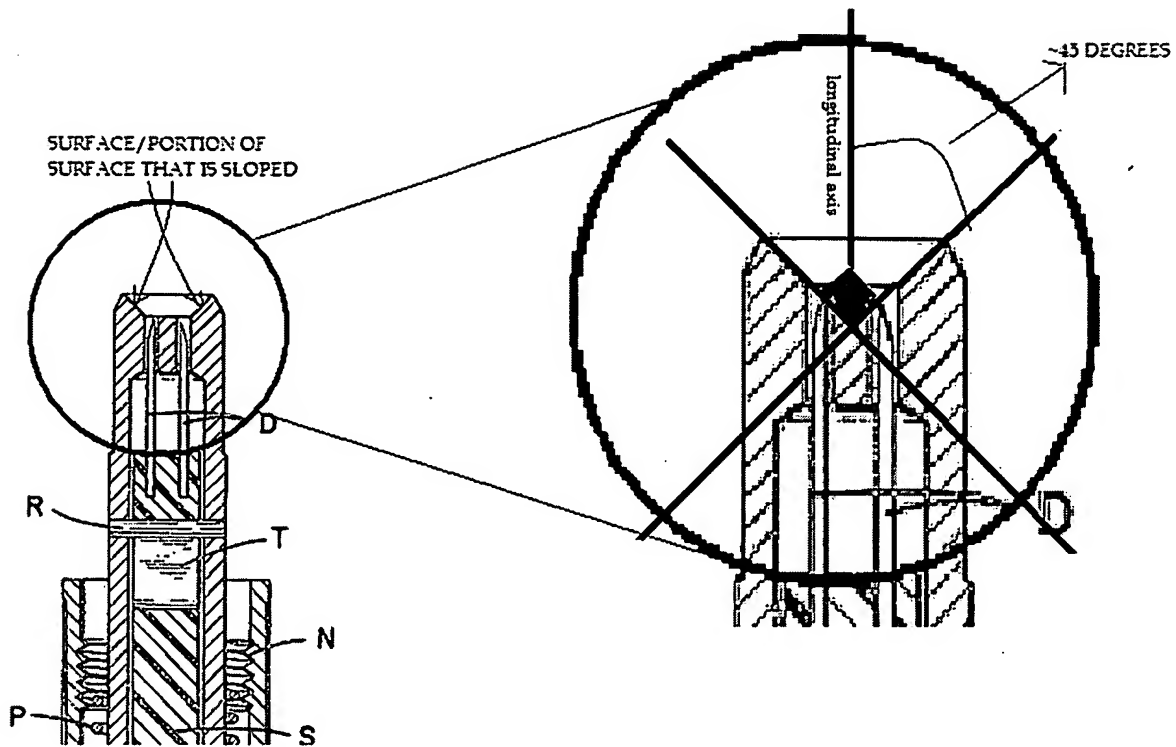
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 1/17/07  
Shumaya B. Ali  
Examiner  
Art Unit 3771

  
JUSTINE R. YU  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

1/19/07



PRIOR ART  
4,069,319  
FIG. 3

*Sheng An*  
11/11/07